DEPARTMENT OF SOCIAL AND HEALTH SERVICES MEDICAL ASSISTANCE ADMINISTRATION Olympia, Washington

To: Pharmacies Memorandum No.: 03-58 MAA

All Prescribers **Issued:** August 18, 2003

Managed Care Plans

Regional Administrators For More Information, call:

CSO Administrators 1-800-562-6188

From: Douglas Porter, Assistant Secretary

Medical Assistance Administration

Subject: Suboxone® Added to the Expedited Prior Authorization List for the

Prescription Drug Program

Effective for the week of September 22, 2003 and after, the Medical Assistance Administration (MAA) will add Suboxone® to the Prescription Drug Program's Expedited Prior Authorization List. This numbered memorandum describes MAA's policy for Suboxone®.

FDA Approval of Suboxone®

The U.S. Food and Drug Administration approved Suboxone® for the treatment of opiate dependence in October 2002. Suboxone® contains both buprenorphine and naloxone, and it is intended for stabilization and detoxification. Suboxone® is the first narcotic drug available for the treatment of opiate dependence that can be prescribed in an office setting under the Drug Addiction Treatment Act of 2000.

Who can prescribe Suboxone®?

Under the Drug Addiction Treatment Act of 2000 (DATA), codified at 21 U.S.C. 823(g), prescription use of these products in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence.

See attached Expedited Prior Authorization (EPA) criteria on page 5.

Who is eligible to be prescribed Suboxone®?

Effective the week of September 22, 2003, and after, clients who meet all of the following criteria are eligible to be prescribed Suboxone®:

- A. The medication is prescribed by a certified physician;
- B. The client is certified by the Chemical Dependency Professional (CDP), through the use of the Buprenorphine-Suboxone Authorization form [DSHS 13-720], as currently active in a state-certified, publicly-funded chemical dependency treatment program for primary opioid addiction; AND
- C. The client's DSHS Medical Identification Card lists one of the following medical identifiers: CNP, CNP Children's Health, CHP-CHIP, GA-U, or LCP-MNP. Clients with any of the following identifiers are not eligible: Emergency Medical Only, Family Planning Only, or QMB-Medicare Only.

Effective the week of September 22, 2003, and after, pharmacies with a current Core Provider Agreement with the Medical Assistance Administration may be reimbursed for dispensing Suboxone® to eligible MAA clients.

Physicians, Pharmacies, and CDPs

Once the client, CDP, and physician have agreed to use Suboxone® in the treatment plan, a Buprenorphine-Suboxone Authorization form [DSHS 13-720] must be completed.

- 1. The CDP completes the Agency Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720] verifying that the client is participating in a state-certified, publicly funded chemical dependency treatment program. The CDP has the client complete the Patient Section of the form and keeps a copy of the form.
- 2. The client takes the form to the physician, obtains a prescription for the drug from a physician, and has the physician complete the Physician Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720]. The physician keeps a copy of the form.
- 3. The client takes the Buprenorphine-Suboxone Authorization Form [DSHS 13-720], along with the prescription, to a pharmacy to obtain the medication.
- 4. The pharmacy completes the Pharmacy Section of the Buprenorphine-Suboxone Authorization Form [DSHS 13-720] and maintains the completed form on file.

After the client obtains a prescription for Suboxone®, the physician should confer regularly with the client and the CDP to ascertain how he or she is progressing in treatment. Continued service and treatment plan reviews should be conducted to determine the appropriate level of treatment, progression with the individual treatment plan, and eligibility for take-home medication. The CDP will document the client's participation and progress in Suboxone® therapy in the client's treatment plan and progress notes.

Certified physicians must authorize Suboxone® prescriptions for no more than a 14-day supply at a time. Prescriptions for each 14-day supply may be reordered only after a recheck of urine drug screens for benzodiazepines, amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates is performed.

The prescriber must fax the pharmacy with confirmation that the drug screen has been completed to release the next 14-day supply and retain the fax in the client's file.

Urinalysis

- Urinalysis testing necessary for medical purposes must be ordered by a physician and billed to MAA.
- Non-medical urinalysis testing for detoxification and outpatient chemical dependency treatment is an allowable expense and billed through the county contract.
- Non-medical urinalysis testing for residential chemical dependency treatment is an allowable expense and billed through the DSHS Division of Alcohol and Substance Abuse's (DASA's) residential contract.

Liver function tests must be performed and monitored periodically to guard against buprenorphine-induced hepatic abnormalities.

Pharmacy

To receive reimbursement for filling Suboxone® prescriptions, pharmacies are required to obtain and keep a record of the Buprenorphine-Suboxone Authorization form [DSHS 13-720]. This form must be signed by the client's CDP who attests by their signature that the client is currently participating in treatment. The prescribing physician's signature must be on the form as well. An example of the Buprenorphine-Suboxone Authorization form [DSHS 13-720] is attached. To download a copy of DSHS form 13-720, go to: http://www1.dshs.wa.gov/msa/forms/eforms.html

Suboxone® is recommended to be used for up to six months only; therefore, prescriptions are limited to a period of six months. The medication is limited to a 14-day supply on each fill. Urine drug screens for benzodiazepines, amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates must be done before each Suboxone® prescription is dispensed. In order to release the next 14-day supply, the prescriber must fax the pharmacy with confirmation that the drug screen has been completed. Pharmacies must retain the fax in the client's file. For detailed procedures, please see the attached instructions for completing the Buprenorphine-Suboxone Authorization form [DSHS 13-720].

Resources

MAA recommends that physicians and counselors review the literature on the use of this medication. Additional information is available from the following:

- > FDA info web http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm
- ➤ CSAT Toll Free buprenorphine Info line 1-866-BUP-CSAT
- ➤ CSAT web site & Physician locator http://www.buprenorphine.samhsa.gov/
- ➤ Suboxone® information web site http://www.suboxone.com/Suboxone/
- ➤ Suboxone® Clinical Info Hotline 1-877-SUBOXONE

Replacement Pages

MAA will publish a complete update to the Expedited Prior Authorization List (Section H of MAA's Prescription Drug Program Billing Instructions) under Numbered Memoranda 03-61 MAA. The updated list will reflect the addition of Suboxone® among other updates that will be explained in Numbered Memoranda 03-61 MAA.

To obtain DSHS/HRSA provider numbered memoranda and billing instruction, go to the DSHS/HRSA website at http://hrsa.dshs.wa.gov (click the Billing Instructions and Numbered Memorandum link). These may be downloaded and printed.

Addition to Expedited Prior Authorization List

Drug Code	Criteria
Suboxone® 019	Before the code is allowed, the patient must meet <u>all</u> of the
(Buprenorphine/	following criteria. The patient:
Naloxone)	
	• Is 16 years of age or older;
	• Has a <u>DSM-IV-TR</u> diagnosis of opioid dependence;
	• Is psychiatrically stable or is under the supervision of a
	mental health specialist;
	Is not abusing alcohol, benzodiazepines, barbiturates, or
	other sedative-hypnotics;
	• Is not pregnant or nursing;
	Does not have a history of failing multiple previous opioid against treatments and multiple releases:
	agonists treatments and multiple relapses;Does not have concomitant prescriptions of azole
	antifungal agents, macrolide antibiotics, protease inhibitors,
	phenobarbital, carbamazepine, phenytoin, and rifampin,
	unless dosage adjusted appropriately; and
	Is enrolled in a state-certified chemical dependency
	treatment program.
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	Limitations:
	No more than a 14-day supply may be dispensed at a time; 14
	Urine drug screens for benzodiazepines, wash starting (mathematical properties).
	amphetamine/methamphetamine, cocaine, methadone, opiates, and barbiturates must be done before each
	prescription is dispensed. The prescriber must fax the
	pharmacy with confirmation that the drug screen has been
	completed to release the next 14-day supply. The fax must
	be retained in the pharmacy for audit purposes;
	Liver function tests must be monitored periodically to
	guard against buprenorphine-induced hepatic
	abnormalities; and
	Clients may receive up to six months of buprenorphine
	treatment for detoxification and stabilization.
	Note: A Buprenorphine-Suboxone Authorization Form [DSHS 13-
	720] must be on file with the pharmacy before the drug is dispensed
	(see attached sample).

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